IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GILEAD SCIENCES, INC.,	)	
	)	
Plaintiff,	)	C.A. No. 22-615 (MN)
	)	
v.	)	**PUBLIC VERSION**
	)	
LUPIN LTD., LAURUS LABS LIMITED, and CIPLA LIMITED,	)	
	)	
Defendants.	)	

[PROPOSED] JOINT PRETRIAL ORDER

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On September 29, 2025 at 4:30 p.m., counsel for Plaintiff Gilead Sciences, Inc. ("Gilead") and counsel for Defendant Cipla Limited ("Cipla" or "Defendant") will participate in a Pretrial Conference before this Court pursuant to Rule 16 of the Federal Rules of Civil Procedure, Rule 16.3 of the Local Rules of the District of Delaware, and the Scheduling Order (D.I. 160[1]) entered in this case. The parties submit for the Court's approval this Joint Pretrial Order governing trial of this action, which is currently scheduled to commence on October 6, 2025.

I. NATURE OF THE ACTION

1. This is a civil action for patent infringement filed by Plaintiff Gilead Sciences, Inc. against Defendant Cipla Limited for infringement of U.S. Patent Nos. 9,708,342, 10,385,067, and 11,744,802 ("Asserted Patents"), under 35 U.S.C. § 271.

2. Gilead's infringement claims arise out of Cipla's filing of Abbreviated New Drug Applications ("ANDAs") with the FDA. Cipla seeks approval to market a generic version of BIKTARVY® ("Biktarvy") prior to the expiration of the Asserted Patents.

3. Biktarvy is a tablet for oral use comprising a three-drug combination of bictegravir (BIC), emtricitabine (FTC), and tenofovir alafenamide (TAF). Biktarvy (in the dosage form containing 52.5 mg of bictegravir sodium indicated for patients weighing at least 25 kg) is a bilayer tablet in which the bictegravir sodium is in a first layer, and the tenofovir alafenamide and emtricitabine are in a second layer.

4. Biktarvy is currently indicated as a complete regimen for the treatment of HIV-1 infection in adults and pediatric patients weighing at least 25 kg who have no antiretroviral treatment history or to replace the current antiviral regimen in those who are virologically suppressed (HIV-1 RNA less than 50 copies per mL) on a stable antiretroviral regimen with no

[1] Unless otherwise noted, citations are to C.A. No. 22-615 (MN).

history of treatment failure and no known substitutions associated with resistance to the individual components of Biktarvy. Biktarvy is also indicated as a complete regimen for the treatment of HIV-1 infection in pediatric patients weighing at least 14 kg and less than 25 kg who have no antiretroviral treatment history or to replace the current antiviral regimen in those who are virologically suppressed (HIV-1 RNA less than 50 copies per mL) on a stable antiretroviral regimen with no history of treatment failure and no known substitutions associated with resistance to the individual components of Biktarvy.

5. The FDA's list of "Approved Drug Products with Therapeutic Equivalent Evaluations," also known as the "Orange Book," lists the Asserted Patents (among other patents) in association with Biktarvy. The Orange Book also lists U.S. Patent No. 9,216,996, which expires on December 19, 2033. Cipla included a Paragraph III certification for the '996 patent in its ANDAs pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), and thus the '996 patent is not asserted in this case.

6. Gilead presently asserts infringement of the following claims ("Asserted Claims") against Cipla.

Asserted Patent	Asserted Claims
'342	2, 3
'067	1
'802	1

7. Pursuant to the parties' agreement in Section XI.A, Gilead has dropped its assertion of all other claims of the Asserted Patents.

8. Cipla has stipulated that its submission of ANDA No. 216914 for Cipla's ANDA product constitutes an act of infringement of claim 1 of the '802 patent and claim 2 of the '342

patent and that its ANDA product, upon approval, would infringe claim 1 of the '802 patent and claim 2 of the '342 patent, so long as they are found valid. D.I. 339 ¶¶ 3–4.

9. Gilead and Cipla have stipulated to dismiss all claims, counterclaims, and defenses concerning claims of the '802 patent and U.S. Patent No. 10,547,846 with prejudice other than claim 1 of the '802 patent. D.I. 339 ¶¶ 1–2.

10. Cipla contends that claim 2 of the '342 patent is invalid for obviousness-type double patenting and for lack of enablement. Specifically, for claim 2 of the '342 patent, Cipla contends this claim is invalid for obviousness-type double patenting because it is an obvious variant of claim 2 of the '996 patent, given the combined teaching of the Tivicay Assessment (DTX-0214) and WO '253 (DTX-0212) in light of the accumulated background knowledge of the POSA as of June 20, 2014. Cipla further contends this claim is invalid for obviousness-type double patenting because it is an obvious variant of claim 2 of the '996 patent, given the combined teaching of the Tivicay 2013 Label (DTX-0213), WO '253 (DTX-0212), and WO '764 (DTX-0211), in light of the accumulated background knowledge of the POSA as of June 20, 2014. Cipla also contends that claim 2 of the '342 patent is invalid for lack of enablement because the specification does not enable the POSA to practice its full scope without undue experimentation. Gilead contends that Cipla cannot meet its burden of proof to show invalidity of claim 2 of the '342 patent.

11. Cipla contends that Gilead has not met its burden of proof to show that claim 3 of the '342 patent and claim 1 of the '067 patent would be infringed by Cipla's ANDA product. To accommodate limited trial time, Cipla has agreed to drop its invalidity defenses with respect to claim 3 of the '342 patent and claim 1 of the '067 patent. The dispute at trial on those claims will be limited to infringement.

12. Cipla contends that claim 1 of the '802 patent is invalid for obviousness and obviousness-type double patenting. Specifically, Cipla contends that claim 1 of the '802 patent is rendered obvious by the combination of WO '323 (DTX-0179) and WO '351 (DTX-0111), considered in light of the accumulated background knowledge of the POSA as of November 9, 2015. Cipla also contends that claim 1 of the '802 patent also is invalid for obviousness-type double patenting because it is an obvious variant of claim 19 of the '067 patent when depending from claim 17, given the teaching of WO '351 (DTX-0111) and the Genvoya Assessment (DTX-0176), in light of the accumulated background knowledge of the POSA as of November 9, 2015. Cipla further contends that claim 1 of the '802 patent is invalid for obviousness-type double patenting because it is an obvious variant of claim 19 of the '342 patent when depending from claim 1, given the combined teaching of WO '351 and the Genvoya Assessment (DTX-0176), in light of the accumulated background knowledge of the POSA as of November 9, 2015. Gilead contends that Cipla cannot meet its burden of proof to show invalidity of claim 1 of the '802 patent.

II. PLEADINGS

A. Gilead's Complaints

13. Gilead received a notice letter from Cipla notifying Gilead that Cipla had submitted an ANDA seeking approval to market generic versions of Biktarvy.[2] In particular, Cipla's notice letter was received by Gilead on or about April 1, 2022, and it notified Gilead that Cipla had submitted ANDA No. 216914. In its notice letter, Cipla contended that the '342, '067, and '846 patents are invalid and that the '067 and '846 patents are not infringed.

14. On May 9, 2022, Gilead filed its Complaint against Cipla (among other defendants) for infringement of the '342, '067, and '846 patents based on Cipla's filing of an ANDA under 21

[2] Gilead also received notice letters from Defendants Lupin Ltd. and Laurus Labs Limited. Lupin and Laurus have been dismissed from the case by consent judgments. D.I. 347, 349.

U.S.C. § 355(j)(2)(B), seeking approval to manufacture, import, market, offer to sell, and/or sell a generic version of Gilead's Biktarvy before expiration of the '342, '067, and '846 patents. D.I. 1.

15. Gilead filed a First Amended Complaint on January 18, 2023, adding U.S. Patent No. 9,682,084. D.I. 62.

16. On September 5, 2023, Gilead was granted U.S. Patent No. 11,744,802. The '802 patent was subsequently listed in the Orange Book in association with Biktarvy. After the '802 patent was granted, the parties stipulated to dismiss all claims, counterclaims, and defenses concerning the '084 patent with prejudice, D.I. 166 ¶ 1, and Gilead filed an unopposed motion for leave to amend its First Amended Complaint to add the '802 patent and remove the '084 patent, D.I. 168. On November 16, 2023, Gilead filed its Second Amended Complaint. D.I. 170. Gilead filed a Third Amended Complaint and Fourth Amended Complaint on January 3, 2024, and March 13, 2024, respectively. D.I. 186, 203. Gilead filed its Fourth Amended Complaint after receiving a second notice letter from Cipla concerning the '802 patent, D.I. 203 ¶¶ 88–89.

17. On November 21, 2023, Gilead received a notice letter from Cipla notifying Gilead that Cipla had submitted an ANDA seeking approval to market a generic version of the pediatric dosage form of Biktarvy. In particular, Cipla submitted ANDA No. 218766. Gilead filed a Complaint against Cipla for infringement of the '342 and '067 patents based on Cipla's filing of ANDA No. 218766 under 21 U.S.C. § 355(j)(2)(B), seeking approval to manufacture, import, market, offer to sell, and/or sell generic versions of the pediatric dosage form of Gilead's Biktarvy before expiration of the '342, and '067 patents. That case was captioned as C.A. No. 23-1480 (MN). On April 1, 2024, C.A. No. 23-1480 (MN) was consolidated with C.A. No. 22-615 (MN). C.A. No. 23-1480 (MN), D.I. 21. ¶ 1.

18. The Fourth Amended Complaint is Gilead's operative pleading.

19. Gilead seeks a judgment:

A. that Cipla has infringed one or more of the Asserted Claims;

B. that the effective date of any approval of Cipla's ANDAs is not earlier than the day after the expiration date of the Asserted Patents (or any later date of exclusivity to which Gilead becomes entitled);

C. declaring that the commercial manufacture, use, offer for sale, sale, and/or importation of Cipla's ANDA products would constitute infringement of one or more of the Asserted Claims, or induce or contribute to such conduct, pursuant to 35 U.S.C. § 271(a) and/or (b); and

D. permanently enjoining Cipla from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any of Cipla's ANDA products until the day after the expiration of the Asserted Patents (or any later date of exclusivity to which Gilead becomes entitled).

B. Cipla's Answers and Affirmative Defenses

20. On March 27, 2024, Cipla filed its Answer to Gilead's Fourth Amended Complaint. D.I. 205.

21. Cipla seeks a judgment:

A. Dismissing the Fourth Amended Complaint with prejudice;

B. Finding that Cipla's submission of its ANDAs seeking FDA approval to market its ANDA products will not directly, indirectly, contributorily, and/or by inducement infringe, either literally or under the doctrine of equivalents, claim 3 of the '342 patent and claim 1 of the '067 patent under 35 U.S.C. § 271;

C. Finding that claim 2 of the '342 patent and claim 1 of the '802 patent are invalid for failure to comply with one or more provisions of the United States Code, including but not limited to 35 U.S.C. §§ 103 and/or 112 as well as under the doctrine of obviousness-type double patenting;

D. Finding in Cipla's favor on its third affirmative defense asserting a lack of irreparable harm;

E. Finding in Cipla's favor on its fifth affirmative defense that Gilead has not presented any facts supporting the conclusion that this is an exceptional case and denying any award of attorney's fees under 35 U.S.C. § 285; and

F. Declaring that Gilead's assertion of infringement of any claim of the Asserted Patents that is limited to polymorphic Form I of bictegravir sodium to be exceptional and awarding Cipla its attorney's fees, costs, and expenses associated therewith.

C. Amendments of the Pleadings

22. No party seeks to amend its pleadings at this time.

III. JURISDICTION

23. This action arises under the patent laws of the United States, title 35, United States Code.

24. This Court has subject matter over all claims in this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

25. The parties agree that the Court has personal jurisdiction over all parties for purposes of this action.

26. The parties agree that venue is proper in this District for purposes of this action.

IV. FACTS

A. Uncontested Facts

27. A joint statement of uncontested facts is set forth in **Exhibit 1**. These uncontested facts require no proof at trial and will become part of the evidentiary record in this case.

28. Any party, with prior notice to all other parties, may read any or all of the uncontested facts to the Court, and will be charged for the time used to do so.

B. Contested Facts

29. Gilead's statement of issues of fact that remain to be litigated is attached as **Exhibit 2**.

30. Cipla's statement of issues of fact that remain to be litigated is attached as **Exhibit 3**.

V. ISSUES OF LAW

31. Gilead's statement of issues of law that remain to be litigated is attached as **Exhibit 4**.

32. Cipla's statement of issues of law that remain to be litigated is attached as **Exhibit 5**.

VI. STATEMENT OF INTENDED PROOFS

33. Gilead's statement of intended proofs and relief sought is attached as **Exhibit 6**.

34. Cipla's statement of intended proofs and relief sought is attached as **Exhibit 7**.

VII. WITNESSES

35. In **Exhibit 8**, Gilead identifies the names of the fact and expert witnesses it expects to call or may call at trial, either live or by deposition.

36. In **Exhibit 9**, Cipla identifies the names of the fact and expert witnesses it expects to call or may call at trial, either live or by deposition.

37. Any witness not listed in **Exhibit 8** or **Exhibit 9** will be precluded from testifying, absent good cause shown.

38. Each side will identify any witnesses it expects to call live or by deposition and the order in which it expects to call them by **6:00 p.m.** or **90 minutes** after the conclusion of a trial day, whichever is later, two (2) calendar days before the day the witness is expected to testify. The receiving side will identify any objections to the identified witness(es) by **7:00 p.m.** of the day received or **60 minutes** after receiving the disclosure, whichever is later, and the parties will meet and confer by **8:00 p.m**. that evening or **60 minutes** after objections are sent, whichever is later, to resolve any objections. If good faith efforts to resolve the objections fail, the objecting side will bring its objections to the Court's attention by emailing Judge Noreika's judicial administrator by **7:00 a.m.** on the day the witness is to testify. The email must include when the side expects the witness to testify (e.g., before or after lunch).

A. Live Testimony

39. Any fact witness who testifies live at trial will only be called once and will not be presented by either side by deposition testimony. Notwithstanding these limitations, the parties may use deposition testimony for purposes of impeachment.

40. Any expert witness who offers testimony on both infringement and invalidity may be called twice—once for their testimony on infringement and once for their testimony on invalidity.

B. Testimony by Deposition

41. Deposition testimony that Gilead may offer into evidence, together with Cipla's counter-designations, is in **Exhibit 10**. The sections of testimony on which there remain objections, together with the grounds for the objections, are also identified therein.

42. Deposition testimony that Cipla may offer into evidence, together with Gilead's counter-designations, is in **Exhibit 11**. The sections of testimony on which there remain objections, together with the grounds for the objections, are also identified therein.

43. **Exhibits 10** and **11** contain the maximum universe of deposition designations, counter-designations, and objections to deposition testimony. A key for the parties' objections to deposition testimony is attached as **Exhibit 15**. None of the foregoing will be supplemented without agreement of all parties or leave of the Court for good cause shown.

44. Unless otherwise agreed to by the parties, each side will provide notice of the final remaining pages and lines of each deposition transcript that a side intends to use at trial (other than for impeachment of a witness or cross-examination) by **7:00 p.m.** on October 1, 2025. The other side will identify any remaining objections and counter-designations to the designated testimony by **7:00 p.m.** on October 2, 2025. The proffering side will identify any remaining objections to the counter-designations by **9:00 p.m.** on October 2, 2025. The parties will meet and confer by **1:00 p.m.** on October 3, 2025, in an effort to resolve the remaining objections and any other issues relating to the designated deposition testimony.

45. If there are objections that remain to be resolved, the side calling the witness by deposition will submit the unresolved objections to the Court by emailing Judge Noreika's judicial administrator no later than **7:00 a.m.** two (2) days before the witness is to be called at trial. The joint submission will include: (i) the entire transcript of the witness's testimony that clearly identifies the designations, counter-designations, and pending objections; and (ii) a cover letter identifying the pending objections as well as a brief explanation (i.e., no more than one sentence per objection) of the basis for the objection and the offering side's brief (i.e., no more than one sentence per objection) response.

46. The side offering the testimony is responsible for preparing and providing the edited deposition video and final transcript clip report to the other side by **7:00 p.m.** on the day before the testimony is expected to be played in Court or, if there are remaining objections for the Court to resolve, as soon as any final rulings are obtained from the Court.

47. The side offering the deposition testimony will email Judge Noreika's judicial administrator by **7:00 a.m.** on the day the designations and counter-designations will be read or played with the amount of time to be charged to each side, according to the portions of deposition testimony designated.

48. The offering side will provide the Court with two copies of the final deposition transcript clip report containing all designations to be played.

49. All deposition testimony will be read or played by video in chronological order. The above chronological order requirement does not apply to the use of deposition transcripts or deposition video for impeachment.

50. Deposition video will include subtitles of the testimony at the bottom of the screen that matches the witness's testimony. All colloquy between counsel and objections will be omitted when the designated testimony is played at trial.

51. Each side reserves the right to offer deposition testimony it affirmatively designated as counter-designations even if not separately designated as counter-designations in the party's deposition designation list, subject to any evidentiary objections. For example, if a party withdraws its affirmative deposition designations for a witness when providing notice of the deposition testimony that party intends to use at trial pursuant to the process in ¶ 44, that party can re-designate any of its withdrawn affirmative designations as counter-designations if the other side intends to play deposition testimony from that witness.

52. The parties each reserve the right to offer deposition testimony designated by the other side (whether as a designation or a counter-designation) even if not separately listed on its own deposition designation list, subject to any evidentiary objections.

53. The listing of a deposition designation does not constitute an admission as to the admissibility of the testimony nor is it a waiver of any applicable objection.

54. When the witness is called to testify by deposition at trial, the side calling the witness will introduce the witness's testimony through no more than two sentences providing the name of the witness, the witness's professional role, and the witness's relationship to the subject matter of the litigation. The side calling the witness will provide this introduction in writing to the other side at the same time it discloses testimony it intends to use on October 1, 2025.

55. Failure to comply with these procedures, absent an agreement by the parties and approval by the Court, will result in waiver of the use of the deposition testimony or waiver of objection to the use of the deposition testimony.

C. Impeachment with Prior Inconsistent Testimony

56. Pursuant to Rule 613 of the Federal Rules of Evidence, deposition and other testimony or statements not specifically identified on a party's deposition designation list or exhibit list may be used at trial for the purpose of impeachment, if otherwise competent for such purpose. The Court will rule at trial on any objections based on lack of completeness and/or lack of inconsistency.

D. Scope Objections to Expert Testimony

57. The parties agree that the Court should rule at trial on objections to expert testimony as beyond the scope of prior expert disclosures, taking time from the parties' trial presentation to argue and decide such objections. All time associated with argument and a decision on such objections will be charged to the losing side.

VIII. EXHIBITS

A. Trial Exhibits

58. The joint list of exhibits that the parties intend to offer at trial is attached as **Exhibit 12**. The joint exhibits are identified by JTX numbers.

59. Gilead's exhibit list, along with Cipla's objections, is attached as **Exhibit 13**. Gilead's exhibits are identified by PTX numbers.

60. Cipla's exhibit list, along with Gilead's objections, is attached as **Exhibit 14**. Cipla's exhibits are identified by DTX numbers.

61. A key for the parties' objections to exhibits is attached as **Exhibit 15**.

62. The parties agree that any description of a document on an exhibit list is provided for convenience only and will not be used as an admission or otherwise as evidence regarding the listed document or any other listed document.

63. Demonstrative exhibits the parties intend to use at trial do not need to be described on their respective lists of trial exhibits.

64. The parties agree that exhibits to be used solely for impeachment need not be included on the lists of trial exhibits or disclosed in advance of being used at trial. All exhibits to be used for direct or cross examination must be on the parties' trial exhibit lists.

65. Each side reserves the right to offer trial exhibits set forth in the other side's exhibit list, even if not set forth in its own trial exhibit list or on the joint exhibit list. All objections to such trial exhibits are preserved.

66. On or before the first day of trial, counsel for each side will deliver to the Courtroom Deputy a completed AO Form 187 list for that side. On or before the first day of trial, Gilead will deliver to the Courtroom Deputy a completed AO Form 187 list for the joint exhibits. At this time, Gilead will also provide electronic versions of all trial exhibits.

67. Each side will provide the Courtroom Deputy with electronic versions of all exhibits and demonstratives to be used in connection with the direct and cross examination of each witness by **7:00 a.m.** on the day the direct or cross examination is to occur.

68. No exhibit will be admitted unless offered into evidence through a witness (i.e., a witness must at least be shown the exhibit) via live testimony or designated deposition testimony. Joint exhibits and exhibits not objected to will be automatically received into evidence by the operation of the Final Pretrial Order without the need for additional foundation testimony, provided the exhibit is shown to a witness.

69. Any trial exhibit, once admitted, may be used equally by either side subject to any limitations to its admission into evidence.

70. Complete legible copies of documents may be offered and received into evidence to the same extent as an original unless a genuine question is raised as to the authenticity of the original, or if in the circumstances it would be unfair to admit the copy in lieu of the original. Complete legible copies of United States and foreign patents and/or applications, and the contents of associated file histories, may be offered and received in evidence in lieu of certified copies thereof, subject to all other objections which might be made to the admissibility of certified copies.

71. The parties will use their best efforts to ensure that only one version of a document is admitted into evidence. In order to reduce the number of duplicative exhibits, where a deposition video references a document by deposition exhibit number and that identical document was also marked as a different exhibit number for use at trial, a party will substitute the trial exhibit for the deposition exhibit.

72. Each side will provide a list of exhibits that it intends to use during direct examination of a witness, indicating with which witness the exhibit will be used, by **6:00 p.m.** or

90 minutes after the conclusion of a trial day, whichever is later, on the day before such direct examination is expected to take place. The receiving side should provide any remaining objections to those exhibits by **7:00 p.m.** of the day received or **60 minutes** after receiving the disclosure, whichever is later, and the parties will meet and confer by **8:00 p.m.** that evening or **60 minutes** after objections are sent, whichever is later, to resolve any objections. If good faith efforts to resolve the objections fail, the objecting side will bring its objections to the Court's attention by emailing Judge Noreika's judicial administrator by **7:00 a.m.** on the day the exhibit is to be offered. The email should attach a copy of the objected to document and, if possible, highlight what is being objected to.

73. If a party proposes to read a statement by a party opponent from any request for admission responses, interrogatory responses, or uncontested facts, they will provide notice by **6:00 p.m.** or **90 minutes** after the conclusion of a trial day, whichever is later, on the day before the statement is intended to be used at trial. This notice provision does not apply when a party intends to use the statement during cross examination or for impeachment purposes.

74. If the other side has not objected to the use of an exhibit, a party may use that exhibit during its opening statement without disclosing it to the other side. If a party intends to use an exhibit during its opening statement to which the other side has objected, the party will disclose the exhibit(s) by **12:00 p.m.** on the day before opening statements. If the opposing side continues to object to any such exhibit(s), it will provide any objections by **3:00 p.m.** that day. The parties are to meet and confer to resolve any objections to these exhibit(s) at **5:00 p.m.** If good faith efforts to resolve the objections fail, the side objecting to the exhibit will follow the objection procedure in ¶ 72.

75. Failure to comply with these procedures, absent an agreement by the parties or approval by the Court, will result in waiver of the use of an exhibit or waiver of objection to the exhibit.

B. Demonstrative Exhibits

76. Gilead's demonstrative exhibits will be identified with PDX numbers.

77. Cipla's demonstrative exhibits will be identified with DDX numbers.

78. The parties will exchange demonstratives to be used in opening statements by **12:00 p.m.** on the day before opening statements. The parties will provide any objections to such demonstratives by **3:00 p.m.** that day. The parties are to meet and confer to resolve any objections to the demonstratives for opening statements at **5:00 p.m.** If good faith efforts to resolve the objections fail, the objecting side will bring its objections to the Court's attention by emailing Judge Noreika's judicial administrator by **7:00 a.m.** on October 6, 2025. The email should attach a copy of the objected to demonstrative and, if possible, highlight what is being objected to.

79. Each side will provide demonstrative exhibits to be used during direct examination of a witness, including indicating with which witness the demonstrative exhibits will be used, by **6:00 p.m.** or **90 minutes** after the conclusion of a trial day, whichever is later, on the day before such direct examination is expected to take place. The receiving side should provide any remaining objections by **7:00 p.m.** of the day received or **60 minutes** after receiving the disclosure, whichever is later, and the parties will meet and confer by **8:00 p.m.** that evening or **60 minutes** after objections are sent, whichever is later, to resolve any objections. If good faith efforts to resolve the objections fail, the objecting side will bring its objections to the Court's attention by emailing Judge Noreika's judicial administrator by **7:00 a.m.** on the day the demonstrative is to be used. The email should attach a copy of the objected to demonstrative and, if possible, highlight what is being objected to.

80. The side seeking to use demonstrative exhibits will provide a color representation of the demonstrative exhibits to the other side in PDF or other suitable form in their order of intended use. For video animations, the side seeking to use the demonstrative will provide it to the other side in native format on an external drive or make it available via a secure file share. For physical demonstrative exhibits, the side seeking to use the demonstrative will provide a color representation as an 8.5" x 11" PDF document. For physical demonstratives for which a color representation as a PDF is not feasible, the party must identify it in writing with specificity or by photograph by the disclosure deadline in ¶ 79 and, upon request, make it available for inspection no later than the deadline for objections.

81. Where a demonstrative refers to information found in a trial exhibit, the side offering the demonstrative will disclose to the other side all trial exhibits that form the basis of the demonstrative at the same time the party discloses the demonstrative.

82. The provisions set forth in the preceding paragraphs do not apply to demonstratives created during testimony, demonstratives created live in court, or demonstratives to be used for cross examination, none of which need to be provided to the other side in advance of their use. In addition, blow-ups or highlights of exhibits or parts of exhibits or testimony are not required to be provided to the other side in advance of their use.

83. The parties will not exchange demonstratives to be used at closing.

84. Failure to comply with these procedures, absent an order from the Court or an agreement by the parties, will result in waiver of the demonstrative exhibit or waiver of objection to the demonstrative exhibit.

IX. MOTIONS *IN LIMINE*

85. Gilead's motions *in limine*, along with Cipla's responses thereto, are set forth in **Exhibit 16**.

86. Cipla has not asserted any motions *in limine*.

X. NON-JURY TRIAL

87. The trial will be timed. Unless otherwise ordered, time will be charged to a side for its opening statement; direct and redirect examinations of witnesses it calls; cross-examination of witnesses called by the other side; its argument on any motions for judgment as a matter of law; all sides' argument on objections the losing side raises to another side's deposition designations, exhibits, or demonstrative exhibits; and closings. The Court will determine how time for argument on objections is charged on a case-by-case basis. The Courtroom Deputy will keep a running total of trial time used by counsel. If any side uses all of its allotted trial time, the Court may, at its discretion, terminate that side's trial presentation.

88. This case is currently scheduled for a 5-day bench trial, beginning on October 6, 2025. D.I. 160. Considering the nature and extent of the parties' disputes [**CIPLA:** subject to and without waiving Defendant's Prejudicial Assertion of Redundant claims objections], the parties request 24 hours for trial presentation (12 hours per side), including closing argument, beginning on October 6, 2025.

89. The parties have agreed on the following order of proof:

A. Gilead will present its affirmative case on infringement.

B. Cipla will present its rebuttal case on infringement and affirmative case on invalidity.

C. Gilead will present its rebuttal case on invalidity.

D. Cipla will present its sur-rebuttal case on secondary considerations.

90. The parties propose the following post-trial briefing schedule:

A. On November 10, 2025, each side will file proposed Findings of Fact, separately stated in numbered paragraphs, constituting a detailed listing of

the relevant material facts the side believes it has proven, in a simple narrative form, along with citations to the record. The proposed Findings of Fact will be limited to a maximum of 50 pages. No separate Conclusions of Law should be filed.

B. On November 17, 2025, Gilead will file its post-trial brief on infringement limited to a maximum of 25 pages.

C. On November 17, 2025, Cipla will file its post-trial brief on invalidity limited to a maximum of 25 pages.

D. On December 22, 2025, Cipla will file its rebuttal post-trial brief on infringement limited to a maximum of 25 pages.

E. On December 22, 2025, Gilead will file its rebuttal post-trial brief on invalidity limited to a maximum of 25 pages.

XI. ADDITIONAL MATTERS

A. Narrowing

91. The parties have reached certain agreements to narrow the number of issues for trial. The parties agree that:

A. Gilead asserts only claims 2 and 3 of the ’342 patent against Cipla and agrees to drop all other claims of the ’342 patent against Cipla;

B. Cipla hereby stipulates to infringement of claim 2 of the ’342 patent by Cipla’s ANDA Product so long as that claim is found to be valid and enforceable;

C. Cipla agrees to drop invalidity defenses as it pertains to claim 3 of ’342 patent, leaving for trial the adjudication of whether Cipla’s ANDA Product infringes that claim;

D. Gilead asserts only claim 1 of the ’067 patent against Cipla and agrees to drop all other claims of the ’067 patent against Cipla;

E. Cipla agrees to drop invalidity defenses as it pertains to claim 1 of the ’067 patent, leaving for trial the adjudication of whether Cipla’s ANDA Product infringes that claim;

F. Defendant Cipla will assert 3 invalidity grounds against claim 1 of the ’802 patent and 3 invalidity grounds against claim 2 of the ’342 patent;

G. For “invalidity grounds,” each prior art combination (for § 103/OTDP) qualifies as one “invalidity ground” and each discrete § 112 theory (i.e. indefiniteness, written description, or enablement) qualifies as one “invalidity ground.”

B. Stipulations

92. The following parties’ agreed stipulations for the case are attached as **Exhibit 17**:

A. Stipulation and Order of Dismissal of Certain Claims and Defenses (D.I. 166);

B. Stipulation and Order to Consolidate (D.I. 208);

C. Stipulation and Order Regarding Representativeness of Certain ANDA Products (D.I. 221);

D. Stipulation and Order Regarding Authenticity and Business Record Status of Documents (D.I. 232);

E. Stipulation and Order on Expert Depositions (D.I. 235);

F. Stipulation and Order of Infringement of Certain Claims and Stipulation and Order of Dismissal of Certain Claims and Defenses Specific to Cipla Limited (D.I. 339).

C. Handling of Confidential Information at Trial

93. The parties anticipate that the majority of the trial will be open to the public and not sealed unless a party specifically requests that a particularly sensitive portion be sealed. If a party makes such a request (providing sufficient notice to the other party and the Court), subject to the Court's approval, the courtroom will be cleared of those individuals not qualified under the Protective Order.

D. Dr. MacMillan

94. One of Gilead's expert witnesses, Dr. David MacMillan, has a preexisting commitment out of the country starting on October 8, 2025. Due to this prior commitment, Gilead requests that his trial testimony be completed by the end of the day on October 7, 2025. Gilead has discussed this issue with Cipla, and Cipla does not object. If necessary, the parties agree that Dr. MacMillan can testify out-of-turn so that his testimony is completed on October 7, 2025.

E. Cipla's Allegation of Prejudicial Assertion of Redundant Claims

95. [**CIPLA:** Cipla believes that limited amount of time available for trial in combination with Gilead's assertion of redundant infringement claims forces an unduly prejudicial restriction on trial time. Even with a stipulation of infringement in place for claim 1 of the '802 patent (expiring 8 November 2036) and claim 2 of the '342 patent (expiring 19 June 2035), Gilead additionally asserts claims of infringement of claim 3 of the '342 patent and claim 1 of the '067 patent, both of which carry the limitation of specific x-ray diffraction peaks associated with bictegravir sodium polymorph form I. This will require testimony from numerous additional experts at trial. There is not sufficient time allotted at this trial for this number of witnesses, and it is not possible in the time frame allowed by the Court for this bench trial.

96. Cipla's ability to properly defend itself from Gilead's allegations and also present an adequate trial record establishing invalidity of the claims asserted by clear and convincing

evidence are severely prejudiced by Gilead's assertion of redundant claims. This is especially true in light of Gilead's refusal to accept as uncontested fact an extensive recitation of facts relevant to Cipla's invalidity defenses (specifically, 372 paragraphs), provided to Gilead on August 15, 2025. The facts so listed are not legitimately in dispute, and Gilead's own experts conceded as much in deposition in this case. Establishing record evidence at trial of so many facts that are not in legitimate dispute will further require more time than is available at trial to establish.

97. Despite multiple and repeated attempts to compromise and narrow claims and defenses, Gilead has remained resistant, insisting on asserting redundant claims 3 of the '342 patent, and claim 1 of the '067 patent, in contravention of the Hatch-Waxman Act. *See* 21 U.S.C. § 355(j)(5)(B)(iii) (directing parties to "reasonably cooperate" in expediting adjudication of claims before the District Court in Hatch-Waxman based litigations). Further, Cipla recognizes parties in "hundreds if not thousands" of other Hatch-Waxman cases have been required to, and have successfully completed, bench trials with similar time limits. This fact does not justify, nor sanction, Gilead's unreasonable conduct in this case.]

98. [**GILEAD**: Gilead is only asserting four claims across three patents against Cipla. This is not an outsized number of claims. Further, if Cipla would narrow its invalidity positions down from three different theories per claim, the case would be narrowed.

99. The Asserted Claims are not redundant. Gilead has good reasons to assert both claims 2 and 3 of the '342 patent. One claims crystalline bictegravir sodium (claim 2 of the '342 patent). The other claims a particular polymorphic form of crystalline bictegravir sodium (claim 3 of the '342 patent). Cipla alleges that claim 2 of the '342 patent is invalid and claim 3 is not infringed. Claim 1 of the '067 patent, on the other hand, recites a method for treating an HIV infection in a human. The dispute on claim 1 is limited to infringement under the doctrine of

equivalents, in contrast to Gilead's theory of literal infringement for claim 3 of the '342 patent. Cipla does not contend that claim 1 of the '067 patent is invalid.

100. Gilead also disagrees with Cipla's characterization of the parties' discussions related to the uncontested facts. Cipla served a 91-page document with 372 paragraphs of "facts" it identified as potentially contested or uncontested. These "facts" were not simply "relevant to Cipla's invalidity defenses," as Cipla contends, but were a recitation of Cipla's invalidity theories. Gilead explained that while there may be uncontested facts that it could agree to in the draft, such as the dates when certain drugs were approved, Cipla had expanded its proposed "facts" to include argument and characterizations of the evidence that Gilead could not agree to. Gilead further explained that if Cipla removed the argumentative language or proposed a narrowed set of truly uncontested facts (as Gilead had done for uncontested facts related to infringement), that Gilead would consider including those as uncontested facts. Cipla refused, maintaining its proposed facts as written.

101. Cipla's argument here is baseless. Hatch-Waxman litigants, both branded companies and generic, are subject to equal time limits, and similar limits have been imposed in hundreds if not thousands of cases. And many of those cases involved more claims than Cipla is concerned about in this case. *See e.g.*, *Cephalon, Inc. v. Slayback Pharma Ltd. Liability Co.*, No. 17-1154-CFC, 2020 WL 3640046, at *1–2 (D. Del. July 6, 2020) (eleven claims asserted in ANDA trial); *Vanda Pharms. Inc. v. West-Ward Pharms. Int'l Ltd.*, 887 F.3d 1117, 1120 (Fed. Cir. 2018) (affirming judgment on thirteen claims following ANDA trial).]

XII. SETTLEMENT CERTIFICATION

102. Pursuant to Local Rule 16.3(c)(12), the parties certify that they have engaged in a good faith effort to explore the resolution of the matter by settlement. No agreement has been reached.

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September 22, 2025

SO ORDERED this _____ day of _____, 2025.

_____
UNITED STATES DISTRICT JUDGE